

### **REMARKS**

Reconsideration is respectfully requested. Claims 1, 4, 9, 12, 15, 17-19, 22-25, and 27-33 are pending. Claims 1, 9, 18, 19, and 30 have been amended. Claims 2, 3, 5-8, 10, 11, 13, 14, 16, 20, 21, and 26 have been canceled. Claims 18, 19, and 22-25 are withdrawn. New claim 31-33 have been added. No new matter has been added due to the amendments. Amendment to and cancellation of the claims does not affect inventorship.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

#### **Claim Amendments**

Claims 18 and 19 have been amended to correct informalities. Claim 30 has been amended for technical clarity.

New claims 31-33 recite "residues 24-295 of SEQ ID NO:3." As the Examiner can appreciate, residues 1-31 of SEQ ID NO:3 comprise of the His tag, the first spacer region, the TEV recognition site and a second spacer region. The specification discloses that the tag was subsequently removed by cleavage with TEV protease. See paragraph [00195]. Applicants submit that it is well known in the art that rTEV is a site specific protease that is known to cleave the gln and gly of the seven amino acid recognition site resulting in a gly at the amino terminus of the protein of interest. Thus one of ordinary skill in the art would understand that the fusion protein (SEQ ID NO:3) was cleaved between the gln23 and gly24 forming the protein consists of residues 24-295 of SEQ ID NO:3. As such, no new matter is added because of the phrase "residues 24-295 of SEQ ID NO:3," and Applicants respectfully request the amendments be entered.

#### **Sequence Compliance**

The Examiner states that the application fails to comply with the requirement of 37 CFR 1.821 through 1.825.

The specification has been amended to include the sequence identifier in the Brief Description of Drawings with regards to the amino acid sequence disclosed in Figure 3. As such, Applicants submit that

the application, as amended, complies with the requirement of 37 CFR 1.821 through 1.825, and respectfully request the objection be withdrawn.

**Claim Rejections - 35 U.S.C. § 101**

Claim 30 stands rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 30 is amended to recite "A protein consisting of residues 125-391 of SEQ ID NO:1." Applicants believe the amendment obviates the rejection.

**Claim Rejection - 35 U.S.C. § 112, First Paragraph**

Claims 1, 4-6, 9, 12-15, 17, and 26-30 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description and enablement requirements. Applicants respectfully traverse.

Claims 5, 6, 13, 14, and 26 have been canceled, rendering the rejections moot.

With regards to claims 1 and 9 (and claims dependent therefrom), the claims have been amended to recite the space group and unit cell dimensions, and as such, Applicants believe the rejections under 112, first paragraph for lacking written description and enablement should be withdrawn.

With regards to claims 17 and 30, the application meets the written description requirement because the application is sufficient to show that the inventor possessed the claimed invention. Applicants respectfully direct Examiner's attention to Example 13 of *Synopsis of Application of Written Description Guidelines* ("Guidelines").

Claim 1 of Example 13 claims "A isolated protein having SEQ ID NO: 3," where the specification has a working example showing the isolated protein was sequenced and determined to consist of SEQ ID NO:3. As stated in the Guidelines:

A search of the prior art indicates that SEQ ID NO: 3 is novel and nonobvious. The claim is directed to a genus of proteins that comprise SEQ ID NO :3. One member of the genus, SEQ ID NO: 3, is described by a complete structure.

The Guidelines go on to conclude:

The claimed subject matter is adequately described. A rejection under the written description requirement should not be entered.

Applicants submit that the instant application is substantial identical to Example 13. As such, instant claims 17 and 30 meet the written description requirement, and the rejection on this basis should be withdrawn.

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Applicants further submit that the instant application also meets the enablement requirement because, as discussed above, the instant application not only discloses working examples, but also discloses how to make variants. The disclosure, taken in view of the general knowledge, enables a skilled artisan to practice the claimed invention without undue experimentation. As such, the rejection based on lacking of enablement is improper and should be withdrawn.

**Claim Rejections - 35 U.S.C. § 102**

Claim 30 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Plowman et al. (U.S. Patent No. 5,962,312) ("*Plowman*"). Applicants respectfully disagree.

Claim 30, as amended, recites "A protein consists of residues 125-391 of SEQ ID NO:1." In contrast, *Plowman* only discloses the full length protein. As such *Plowman* does not anticipate claim 30, and Applicant respectfully request the rejection be withdrawn.

**CONCLUSION**

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 442-1000.

Respectfully submitted,  
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